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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,975	07/03/2003	Donald L. Wise	CSI 130	8618

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PATREA L. PABST
PABST PATENT GROUP LLP
400 COLONY SQUARE
SUITE 1200
ATLANTA, GA 30361

EXAMINER	
SHAHNAN SHAH, KHATOL S	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 11/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	10/613,975	WISE ET AL.	
	Examiner	Art Unit	
	Khatol S Shahnan-Shah	1645	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 10 August 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☒ Applicant's reply has overcome the following rejection(s): 102 rejection.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *outstanding rejection under 112 first paragraph*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: *None*.

   Claim(s) objected to: *None*.

   Claim(s) rejected: *1,3 -11*.

   Claim(s) withdrawn from consideration: *None*.

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

Attachment to Advisory Action

1. Applicants' amendments and response to a final action, under 37 CFR 1.116, received 8/10/2004 are acknowledged. Claims 1, 3, 6 and 7 have been amended. The amendments has been entered. Claim 2 has been canceled.

2. Currently claims 1, 3-11 are pending and under consideration.

Note: Clarification in regard to status of claim 6.

Applicants' listing of the claims faxed August 10, 2004 lists claims 6 as "currently amended". But applicants' remark on page 4 recites that claims 1, 3-5 and 7-11 are pending upon entry of this amendment. This issue was clarified on a telephonic interview with applicants' attorney Rivka Monheit on 11/1/04. Claim 6 is still pending in this application and Ms Monheit mentioned that there has been a typographical error on page 4 of the response omitting claim 6.

Rejections Moot

3. Rejection of claim 2 under 35 U.S.C. 112 first paragraph made in paragraph 9 of the office action mailed December 22, 2003 is moot in view of applicants' cancellation of said claim.

4. Rejection of claim 2 under 35 U.S.C. 102(b) made in paragraph 13 of the office action mailed December 22, 2003 is moot in view of applicants' cancellation of said claim.

Rejections Withdrawn

5. Rejection of claims 1, 3-5 and 8-11under 35 U.S.C. 102(b) made in paragraph 13 of the office action mailed December 22, 2003 is withdrawn in view of applicants' amendments.

Rejections Maintained

6. Rejection of claims 1, 3-11 under 35 U.S.C. 112 first paragraph made in paragraph 9 of the office action mailed December 22, 2003 is maintained.

Applicants argue that best evidence against the examiner's rejection is the prior article by O'Hagan, J. Pharm.Pharmacol. 50:1-10 (1997), makes clear that even as of 1997, nucleic acid vaccines, while not being perfect and have some FDA issues, were effective and could be delivered using a polymer carrier. Applicants further argue that additional papers are enclosed to show that DNA vaccines are considered to be enabled and vaccination with them does not require " undue experimentation".

Applicants' arguments have been fully considered but they are not persuasive because it appears that the applicants' arguments are focused on general enablement of DNA vaccines. However, the instant rejection is focused on the broad scope of the claims encompassing all pathogens. The examiner hereby clarifies the issues involving this rejection. The scope of the claims specially the base claim 1 is broad which includes all pathogens from prokaryotic to eukaryotic i.e. bacteria, virus, parasites and fungi, including intracellular and extra cellular pathogens. The specification, while being enabled for a composition inducing immune response against certain pathogens, does not reasonably provide enablement for a vaccine for inducing immune response against all pathogens. The claims are very broad and drawn to a vaccine, which encompasses any/all pathogens.

Applicants' specification fails to provide guidance to the skilled artisan on the parameters for DNA vaccine for the breadth of the claimed invention (i.e. all pathogens). Numerous factors complicate the DNA vaccine therapy art, which have not been shown to be overcome by routine experimentation. These include, the fate of the DNA vector itself (volume of distribution, rate of clearance into the tissues, etc.), the *in vivo* consequences of altered gene expression and protein function, the fraction of vector taken up by the target cell population, the trafficking of the genetic material within cellular organelles, the rate of degradation of the DNA, the level of mRNA produced, the stability of the mRNA produced, the amount

and stability of the protein produced, and the protein's compartmentalization within the cell, or its secretory fate, once produced. These factors differ dramatically based on the vector used, the protein being produced, and the disease being treated as evidenced by applicants' own cited prior art (i.e. different pathogens bacterial vs eukaryotes, see Barnes et al. Curr. Opin. Mol. Ther. 2000). Additionally, the specification does not provide any working examples which enable the claimed invention. Nor does the specification provide any guidance to the skilled artisan on how to make and use genetic constructs of all pathogens which would result in the desired effect for that specific pathogen, in the absence of particular guidance, the artisan would have been required to develop *in vivo* and *ex vivo* means of practicing the claimed invention and such development in the nascent and unpredictable DNA vaccination art would have been considered to have necessitated undue experimentation without a reasonable expectation of success on the part of the practitioner.

A disclosure in an application, to be complete, must contain such description and details as to enable any person skilled in the art or science to which it pertains to make and use the invention as of its filing date, In re Glass, 181 USPQ 31; 492 F2.d 1228 (CCPA 1974). While the prior art setting may be mentioned in general terms, the essential novelty, the essence of the invention, must be described in such details, including proportions and techniques where necessary, as to enable those persons skilled in the art to make and utilize the invention.

Conclusions

7. No claims are allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol S Shahnan-Shah whose telephone number is (571)-272-0863. The examiner can normally be reached on 7:30am-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith can be reached on (571)-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

Art Unit 1645

November 1, 2004

RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER